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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,584	12/20/2001	Michael V. Chobotov	24641-1120	4975

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/029,584

Applicant(s)

CHOBOTOV ET AL.

Examiner

Urmi Chattopadhyay

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-20,22-29,31-37,62-64,66,69,71 and 74-95 is/are pending in the application.
- 4a) Of the above claim(s) 7-10,26-29,36 and 79-82 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 69,71,93 and 94 is/are allowed.
- 6) ☒ Claim(s) 1,3-6,12-20,22-25,31-35,37,62,63,74-78,83-92 and 95 is/are rejected.
- 7) ☒ Claim(s) 64 and 66 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendment filed 8/24/05 has been entered. Claims 1, 3-10, 12-20, 22-29, 31-37, 62-64, 66, 69, 71 and 74-95 are currently pending, of which claims 7-10, 26-29, 36 and 79-82 remain withdrawn from consideration. The claims being considered for further examination on the merits are 1, 3-6, 12-20, 22-25, 31-35, 37, 62-64, 66, 69, 71, 74-78 and 83-95.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-5, 12-20, 22-24, 31-35, 74-77, 83-90 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. (USPN 6,149,681, as cited in previous office action) in view of Lentz et al. (USPN 6,428,571 as cited in applicant's IDS).

Houser et al. discloses an implantable vascular graft with all the elements of claims 1, 19, 20, 34, 35, 74, 90 and 95, but is silent to the flexible material portion comprising a plurality of layers and the flap of flexible material being secured to another layer. See Figure 9 for at least one flap (92) of the flexible material being folded back and secured to itself to form a loop portion about an expandable (column 7, lines 20-22 and column 8, lines 7-8) transversely oriented member/connector member/member (90). The method of forming a joint disclosed in

Art Unit: 3738

column 8, lines 33-51 of fixing a flap (92) of the flexible material portion (80) about at least a portion of the transversely oriented member/connector member (90) provides a configuration that is inherently capable of transferring the tensile force on the transversely oriented member/connector member into a shear component of force on the fixed portion of the flap.

Lentz et al. teaches an implantable vascular graft (10) with a flexible material portion comprising two layers (12, 14). The inner layer (14) is made from ePTFE with a large internodal distance in order to provide a porosity sufficient to promote cell endothelialization, tissue ingrowth and healing. The outer layer (12) is made from ePTFE with a smaller internodal distance in order to provide enhanced radial strength. The multi-layer composite graft exhibits long-term patency and overall superior radial tensile strength. See Figures 1 and 2, abstract and column 4, lines 33-60. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lentz et al. to modify the vascular graft of Houser et al. by having the flexible material portion comprise two layers, specifically an ePTFE inner layer with large internodal distance and an ePTFE outer layer with smaller internodal distance, in order for the composite graft to exhibit long term patency and overall superior radial tensile strength. When the two-layered flap of flexible material is folded back to form a loop portion about the transversely oriented member/connector member/member, the flap will comprise a layer (outer layer 12) that is secured to itself and another layer (inner layer 14).

Claims 3, 4, 22, 23, 75 and 76, see column 7, lines 19-20 and 50-58 for transversely oriented member/connector member comprising a material, nickel titanium, having a higher strength relative to the strength of the flexible material.

Claims 5, 24 and 77, see column 8, lines 47-49 for securing the flap by bonding with an adhesive to the flexible material of the graft.

With respect to claims 12, 31 and 83, Houser et al. does not disclose the at least one flap being specifically about 1 to 25 square millimeters. In Figure 8 of Houser et al., it is clear that the length of the flap (92) corresponds to the length of the top of the transversely oriented member/connector member/member around which the loop is formed. Because the length of top of the transversely oriented member/connector member/member determines the circumference of the vascular graft formed, variation in the length will provide grafts of different diameters made for different sized vessels. A graft having a small diameter will therefore have a small flap area. Because the size of the graft will depend on the needs of the individual patient, it is obvious that the flap area required by claims 12, 31 and 83 will be met by the implantable vascular graft of Houser et al.

Claims 13, 14, 32, 33, 84 and 85, see Figure 8 and column 8, lines 39-51 for the joint comprising a plurality of flaps, one flap around each of the top and bottom transversely oriented member/connector member/member (90), folded back and secured to itself to form loop portions about the transversely oriented member/connector member/member.

Claims 15-18 and 86-89, see abstract, column 7, lines 20-22 and column 8, lines 7-8 for transversely oriented member/member limitations.

4. Claims 6, 25, 37 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houser et al. and Lentz et al. as applied to claims 5, 24, 35 and 77 above, and further in view of Edwin et al. (USPN 6,245,099 as cited in previous office action).

Houser et al., as modified by Lentz et al., discloses an implantable vascular graft with all the elements of claims 5, 24, 35 and 77, but is silent to the adhesive being FEP or PFA, as required by claims 6, 25, 37 and 78 and of the flexible material portion comprising ePTFE, as also required by claim 37. Edwin et al. teaches a graft wherein FEP is introduced between layers of ePTFE in order to selectively bond the layers together. See column 8, lines 40-45. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Edwin et al. to use FEP as the adhesive in Houser et al. to secure the flap to the flexible material because the graft of Houser et al., as modified by Lentz et al., is a multi-layer ePTFE graft, and it is well known in the art that FEP effectively bonds ePTFE to ePTFE. This will prevent the flap from separating from the flexible material during use.

5. Claims 62 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Layne (USPN 6,558,414 as cited in applicant's IDS) in view of Lentz et al.

Layne discloses an endovascular graft with all the elements of claims 62 and 91, but is silent to the flexible material portion comprising a plurality of layers and the flap of flexible material being secured to another layer. See Figure 4 and columns 3-4, lines 57-6 for a generally tubular flexible material portion (20) and a serpentine expandable member (30) circumferentially oriented about a circumference of the generally tubular flexible material portion (20). The expandable member (30) is secured to the generally tubular flexible material portion with a joint that includes at least one flap (50) of the flexible material folded back to form a loop portion about the serpentine expandable member (30). See column 4, lines 51-56 for the flap of flexible material comprising a layer that is secured to itself. Lentz et al. teaches an implantable vascular

Art Unit: 3738

graft (10) with a flexible material portion comprising two layers (12, 14). The inner layer (14) is made from ePTFE with a large internodal distance in order to provide a porosity sufficient to promote cell endothelialization, tissue ingrowth and healing. The outer layer (12) is made from ePTFE with a smaller internodal distance in order to provide enhanced radial strength. The multi-layer composite graft exhibits long-term patency and overall superior radial tensile strength. See Figures 1 and 2, abstract and column 4, lines 33-60. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lentz et al. to modify the vascular graft of Layne by having the flexible material portion comprise two layers, specifically an ePTFE inner layer with large internodal distance and an ePTFE outer layer with smaller internodal distance, in order for the composite graft to exhibit long term patency and overall superior radial tensile strength. When the two-layered flap of flexible material is folded back to form a loop portion about the expandable member, the flap will comprise a layer (outer layer 12) that is secured to itself and another layer (inner layer 14).

6. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Layne and Lentz et al. as applied to claim 62 above, and further in view of Lombardi (WO 01/58384 A1, as cited in previous office action).

Layne, as modified by Lentz et al., discloses an endovascular graft with all the elements of claim 62, but is silent to the additional limitation of at least some of the apices in the first set of apices further comprising connector elements that extend in a direction substantially parallel to the longitudinal axis of the generally tubular flexible material portion and beyond an edge of the generally tubular flexible material portion, as required by claim 63. See Figures 2 and 4 for

Art Unit: 3738

the serpentine expandable member comprising first and second sets of apices directed in substantially opposite directions. Lombardi teaches a stent-graft wherein the stent apices (70) comprise connector elements (74) that extend in a direction substantially parallel to the longitudinal axis of the stent and have spherical beads (76) welded thereto. See Figures 13-15 and pages 19-20, lines 20-3. By virtue of the rounded surface and greater thickness of the spherical bead (76) relative to the stent struts (54), the apices (70) defining the end of the stent are less likely to cause trauma in the bodily tissue in which the apices (70) are embedded, than if the connector elements (74) and beads (76) were absent. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Lombardi to modify the first set of apices of Layne by including connector elements that extend in a direction substantially parallel to the longitudinal axis of the generally tubular flexible material portion and to weld spherical beads having a thickness greater than the thickness of the serpentine expandable member to the connector elements in order to reduce the likelihood of the first set of apices causing trauma to the vessel in which it is implanted. Because at least some of the first set of apices of Layne are exposed (not completely enclosed by the flexible material), the connector elements with beads extending therefrom will extend beyond an edge of the generally tubular flexible material portion.

7. Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Layne in view of Lentz et al. as applied to claim 91 above, and further in view of Edwin et al.

Layne, as modified by Lentz et al., discloses an endovascular graft with all the elements of claim 91, but is silent to the additional limitation of the serpentine expandable member



Art Unit: 3738

comprising a self expanding stent, as required by claim 92. See column 3, lines 18-19 for the serpentine expandable member being a metal stent. Edwin et al. teaches that self-expanding stents have an inherent resiliency that allows them to recover once a compressive force that results in deformation is removed, as opposed to balloon-expandable stents that deform and do not recover once compressive forces exceed their hoop strength. See column 5, lines 20-33. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Edwin et al. to make the metal stent of Layne self-expanding so that it can recover once a compressive force that results in deformation is removed.

#### *Allowable Subject Matter*

8. Claims 69, 71, 93 and 94 are allowed.
9. Claims 64 and 66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### *Response to Arguments*

10. Applicant's arguments filed 8/24/05 have been fully considered but they are not persuasive. Applicant states "the Examiner appears to assume, without specific support in the prior art, that both layers of a two-layered graft would be utilized in forming a loop as recited in the claims". In response, applicant's attention is directed to column 5, lines 51-54 of Lentz et al. The outer tube (12) and inner tube (12) forming the two layers of the graft (10) are sintered together, which serves to "adheringly bond the interface (13) between the two tubes, resulting in

Art Unit: 3738

a single composite structure". When the single layer flexible material of Houser et al. and Layne is replaced with the composite structure of Lentz et al., the flap of flexible material that is folded back to form a loop portion will indeed include both layers because they are sintered together. As stated in the rejection above, the motivation to replace the single layer flexible material of Houser et al. and Layne with the two-layer composite of Lentz et al., specifically an ePTFE inner layer with large internodal distance and an ePTFE outer layer with smaller internodal distance, is to impart long term patency and overall superior radial tensile strength to the vascular graft. It certainly would have been obvious to one of ordinary skill in the art to fold back both layers to form the loop because not only are they sintered together, their combination provides the aforementioned advantage over the single layer flexible material. So while a single layer is sufficient to secure the rectangular frame of Houser et al. to the graft material and is sufficient for folding back over and weaving between adjacent stents to produce the encapsulated stent of Layne, there is motivation to fold over both layers. The motivation is their combination exhibits long-term patency and overall superior radial tensile strength. Also, it would have been counterintuitive to one of ordinary skill in the art to separate the sintered layers in order to form a loop from a single layer flap of flexible material when including both layers in the loop not only does not destroy the vascular graft or its functioning in any way but also provides an advantage. When the two-layered flap of flexible material is folded back to form a loop portion about the transversely oriented member/connector member/member, the flap will comprise a layer (outer layer 12) that is secured to itself and another layer (inner layer 14). The claims do not require that the "another layer" be separate from any of the plurality of layers that make up the flap of flexible material. Also in response to applicant's argument that there is no motivation to use both


Art Unit: 3738

layers of Lentz's graft for forming the flap of Houser et al. or Layne, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

*Conclusion*

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.



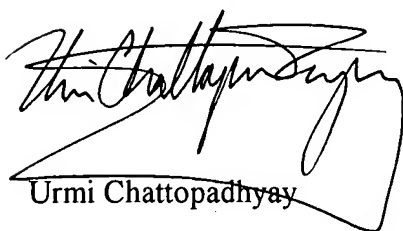
David J. Isabella  
Primary Examiner

Art Unit: 3738

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

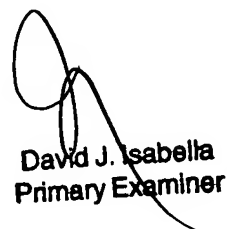
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay

Art Unit 3738



David J. Isabella  
Primary Examiner